Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® stage I breast carcinoma.

BIBLIOGRAPHIC SOURCE(S)

Harvey JA, Bassett LW, Evans WP III, Brenner RJ, Comstock CE, D'Orsi CJ, Edge SB, Everson LI, Huynh PT, Jong RA, Lehman CD, Mahoney MC, Morris EA, Rabinovitch R, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® stage I breast carcinoma. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 5 p. [32 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Harvey JA, Bassett L, Birdwell RL, Brenner RJ, Comstock CE, D'Orsi C, Jong RA, Mahoney MC, Morris EA, Edge SB, Expert Panel on Women's Imaging - Breast Work Group. Stage 1 breast carcinoma. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 4 p. [30 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Stage I breast carcinoma

GUIDELINE CATEGORY

Evaluation
Screening

CLINICAL SPECIALTY

Internal Medicine
Obstetrics and Gynecology
Oncology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for the imaging work-up of asymptomatic women with stage I breast carcinoma

TARGET POPULATION

Asymptomatic women with stage I breast carcinoma

INTERVENTIONS AND PRACTICES CONSIDERED

1. X-ray
    - Whole body
    - Chest
2. Technetium (Tc)-99m
    - Bone scan whole body
    - Sulfur colloid liver scan
3. Computed tomography (CT)
    - Chest with or without contrast
    - Abdomen with or without contrast
    - Head with or without contrast
4. Magnetic resonance imaging (MRI)
    - Abdomen with or without contrast
    - Head with contrast
5. Fluorodeoxyglucose-positron emission tomography (FDG-PET) whole body
6. Ultrasonography (US) abdomen

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid, but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the American College of Radiology (ACR) Appropriateness Criteria® Evidence Table Development document (see "Availability of Companion Documents" field).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Modified Delphi Technique

When the data available from existing scientific studies are insufficient, the American College of Radiology Appropriateness Criteria (ACR AC) employs systematic consensus techniques to determine appropriateness. The ACR AC panels use a modified Delphi technique to determine the rating for a specific procedure. A series of surveys are conducted to elicit each individual panelist’s expert opinion of the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario based on the available data. ACR staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. Voting surveys are

completed by panelists without consulting other panelists. The ratings are integers on a scale between 1 and 9, where 1 means the panel member feels the procedure is "least appropriate" and 9 means the panel member feels the procedure is "most appropriate." Each panel member has one vote per round to assign a rating. The surveys are collected and de-identified and the results are tabulated and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized, and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. If eighty percent (80%) of the panel members agree on a single rating or one of two consecutive ratings, the final rating is determined by the rating that is closest to the median of all the ratings. Up to three voting rounds are conducted to achieve consensus.

If consensus is not reached through the modified Delphi technique, the panel is convened by conference call. The strengths and weaknesses of each imaging examination or procedure are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Stage I Breast Carcinoma

Variant 1: Rule out metastases - asymptomatic woman.

Radiologic Procedure	Rating	Comments	RRL*
Rule Out Bone Metastases			
Tc-99m bone scan whole body	2		Med
X-ray radiographic survey whole body	2		Med
FDG-PET whole body	2		High
Rule Out Thoracic Metastases			
X-ray chest	2		Min
CT chest with or without contrast	2		Med
X-ray tomography chest	2		Low
FDG-PET whole body	2		High
Rule Out Liver Metastases			
CT abdomen with or without contrast	2		Med
Tc-99m sulfur colloid scan liver	2		Med
US abdomen	2		None
MRI abdomen with or without contrast	2		None
FDG-PET whole body	2		High
Rule Out Brain Metastases			
MRI head with contrast	2		None
CT head with or without contrast	2		Med
FDG-PET whole body	2		High

Radiologic Procedure	Rating	Comments	RRL*
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Staging parameters for breast cancer according to the TMN classification of the American Joint Committee on Cancer include T, the local extent of disease; N, the presence of regional lymph node metastases; and M, the presence of distant metastases. A diagnosis of stage I breast cancer indicates surgical removal of an invasive breast carcinoma that is 2 cm or smaller in diameter (T1), which has no regional (axillary) lymph node metastases (N0) and no distant metastases (M0).

The most common sites for distant metastases from breast carcinoma are the skeleton, lung, liver, and brain. Several imaging examinations are available that can potentially identify metastases to these organs. Surveys of patients with breast cancer indicate that most of them prefer an intensive follow-up to detect asymptomatic disease, including metastases. Surveys of physicians who take care of patients with breast cancer indicate that most of these physicians also favor intensive surveillance programs in patients with breast cancer who are asymptomatic. However, because of cost constraints, there should be a reasonable anticipated yield and an expected effect on patient management and outcome when imaging examinations are ordered on asymptomatic patients with breast cancer. In a Cochrane Collaboration Review of four randomized, controlled clinical trials that included 3,055 women, no difference was found in overall or disease-free survival for women who underwent intensive radiologic and laboratory testing compared with those managed with clinical visits and mammography. This appropriateness guideline segment addresses the imaging workup of women with stage I breast carcinoma—specifically, which imaging tests should be done to rule out unexpected metastatic disease.

Skeletal Metastases

Radionuclide scanning is more effective than conventional radiography for detecting skeletal metastases because radionuclide scans have higher sensitivity and can survey the entire skeleton in one examination. However, several investigations that are discussed below have revealed that bone scanning is not useful in stage I breast carcinoma because of its low yield and lack of proven effect on management or survival.

A multicenter study in Italy randomized 1,320 women into a study group that would undergo "intensive surveillance" and a control group having only tests that were ordered as a result of subsequent clinical findings uncovered at routine medical visits. The intensive surveillance included radionuclide bone scanning, chest radiography, and liver ultrasonography (US). The study, which included 739

node-negative women, found that metastases of all kinds were found only an average of one month earlier in the intensive surveillance group. The earlier detection of these metastases had no significant effect on overall survival.

A second large clinical trial in Italy randomized 1,243 women into "intensive" and "clinical" follow-up protocols to determine whether early detection of bone and intrathoracic metastases was effective in reducing mortality in the intensive follow-up group. Fifty-two percent of the women in the latter study were node-negative. Although more bone and lung metastases were found in the intensive follow-up group, there was no significant difference in the overall 5-year survival rates between the two groups.

Another large clinical study (nonrandomized) in Italy confirmed the lack of value of regular preoperative radiography and radionuclide bone scanning performed on consecutive stage I asymptomatic breast cancer patients. Only 1 of 633 patients with stage I disease had metastatic bone disease detected. Several other nonrandomized clinical studies with many subjects have also documented the low yield and lack of utility of radionuclide bone scanning for patients with stage I breast carcinoma.

Despite the low yield of bone scans, many clinicians have continued to recommend baseline bone scans on the basis that they could be useful for comparison with subsequent scans performed when patients develop symptoms or convert to an abnormal routine scan. In fact, routine baseline bone scans are unlikely to be useful in stage I disease because few patients will later convert to positive scans, and also because studies in the literature show that earlier detection of metastases does not reduce overall mortality. Furthermore, several studies have reported false-positive scans as a problem encountered when screening for metastases in asymptomatic patients. No information is available regarding whether positron emission tomography combined with computed tomography (PET/CT) offers an advantage over current methods for detecting skeletal metastases.

Lung Metastases

Methods for detecting lung metastases include conventional chest radiography and CT. Because of its relatively low cost when compared with the other imaging modalities, conventional chest radiography is considered the most reasonable approach for detecting unsuspected disease, as a baseline for monitoring, and for routine follow-up. CT is more sensitive than conventional whole-lung tomography and is the method of choice to evaluate equivocal findings on chest radiography and to identify additional nodules in positive cases. No information is available regarding whether PET/CT offers an advantage over current methods for detecting lung metastases.

Despite its relatively low cost, investigators have even questioned the use of routine chest radiography to detect intrathoracic metastases in patients with breast cancer, especially those with stage I disease. One problem is its low yield in stage I disease, reported to be less than 0.5% in asymptomatic women who had routine chest radiographs after the diagnosis of stage I breast carcinoma. In a study of 412 women with newly diagnosed breast cancer, chest radiograph only showed metastasis in women previously classified as having stage III disease.

Furthermore, false-positive chest radiographs can lead to expensive diagnostic workups. Two large Italian randomized control studies failed to show a significant outcome benefit when routine chest radiography was used to detect metastases earlier.

Liver Metastases

Both radionuclide scanning and US have been used to detect liver metastases. Although liver metastases are not as common as lung or bone metastases, the appearance of liver metastases is associated with the worst prognosis. To be detected reliably by Tc-99m sulfur colloid liver scans, metastases generally must be larger than 2 cm. US can also identify liver metastases 2 cm or larger, and it is often used to localize these lesions for biopsy or fine-needle aspiration cytology. No information is available regarding whether PET/CT offers an advantage over current methods for detecting liver metastases.

As with screening for bone and lung metastases, the yield of screening with radionuclide scans or US to detect asymptomatic liver metastases is low. In one retrospective study of 234 asymptomatic patients with breast carcinoma at various stages, preoperative radionuclide liver scanning identified metastases in only 1% of the cases. Furthermore, in that study, 8 of 11 positive scans were eventually determined to be false-positives. Another study showed the yield for detecting metastases using radionuclide scans or US to be less than 0.5%. A review of four studies evaluating a total of 423 women with stage I breast carcinoma showed no metastatic lesions on liver US. In a study of 412 women with newly diagnosed breast cancer, liver US only showed metastasis in women previously classified as having stage III disease. Large randomized control studies have failed to show a benefit from screening for liver metastases with US.

Although CT and magnetic resonance imaging (MRI) may show more lesions than radionuclide scanning or US, there is no evidence in the literature that routine imaging of the liver with either of the more sensitive modalities has clinical utility in asymptomatic patients with breast carcinoma.

Brain Metastases

Breast cancer is second only to lung carcinoma as a cause of intracerebral and orbital metastases, but few patients have brain metastases at the time of breast cancer diagnosis, particularly when the tumor is detected at stage I. In CT examinations, brain metastases may be nodular or ring-shaped, single or multiple; are usually associated with extensive edema; and show varying amounts of enhancement with intravenous contrast agents. One review of patients with breast cancer at all stages having radionuclide brain scanning and CT found that imaging studies failed to identify brain metastases in the absence of neurologic symptoms. Because of its greater sensitivity, MRI has largely replaced CT for detecting and evaluating brain lesions. Gadolinium-enhanced MRI increases the number of suspected cerebral metastases that can be detected. Contrast-enhanced MRI has also been shown to be superior to double-dose delayed CT for detecting brain metastases. However, no studies suggest any usefulness to routine imaging with any modality for detecting cerebral metastases in asymptomatic women with breast cancer. No information is available regarding

whether PET/CT offers an advantage over current methods for detecting brain metastases.

Refer to the original guideline document for a discussion of quality-of-life issues.

Summary

- There are no survival differences between women who obtain intensive screening and surveillance with imaging and laboratory studies compared with women who only undergo testing due to the development of symptoms or findings on clinical examinations.
- Women and health care professionals generally prefer intensive screening and follow-up after a diagnosis of breast cancer. However, quality-of-life is not different for women who undergo intensive screening and surveillance compared with those who do not.
- Given the lack of difference in survival or quality-of-life, there is little justification for imaging to detect or rule out metastasis in asymptomatic women with newly diagnosed stage I breast cancer.

Abbreviations

- CT, computed tomography
- FDG-PET, fluorodeoxyglucose–positron emission tomography
- MRI, magnetic resonance imaging
- Tc, technetium
- US, ultrasound

Relative Radiation Level	Effective Dose Estimated Range
None	0
Minimal	<0.1 mSv
Low	0.1–1 mSv
Medium	1–10 mSv
High	10–100 mSv

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for screening of metastases in asymptomatic women with stage I breast cancer

POTENTIAL HARMS

- Several studies have reported false-positive scans as a problem encountered when screening for metastases in asymptomatic patients.
- False-positive chest radiographs can lead to expensive diagnostic workups.

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, an RRL indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see "Availability of Companion Documents" field).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Harvey JA, Bassett LW, Evans WP III, Brenner RJ, Comstock CE, D'Orsi CJ, Edge SB, Everson LI, Huynh PT, Jong RA, Lehman CD, Mahoney MC, Morris EA, Rabinovitch R, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® stage I breast carcinoma. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 5 p. [32 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2009)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Jennifer A. Harvey, MD (*Principal Author*); Lawrence W. Bassett, MD (*Chair*); W. Phil Evans, III, MD (*Vice-Chair*); R. James Brenner, MD; Christopher E. Comstock, MD; Carl J. D'Orsi, MD; Stephen B. Edge, MD; Lenore I. Everson, MD; Phan Tuong Huynh, MD; Roberta A. Jong, MD; Constance D. Lehman, MD, PhD; Mary C. Mahoney, MD; Elizabeth A. Morris, MD; Rachel Rabinovitch, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria® overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria® literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the ACR Web site.
- ACR Appropriateness Criteria® evidence table development. Reston (VA): American College of Radiology; 4 p. Electronic copies: Available in Portable Document Format (PDF) from the ACR Web site.
- ACR Appropriateness Criteria® radiation dose assessment introduction. American College of Radiology. 2 p. Electronic copies: Available from the ACR Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 30, 2001. The information was verified by the guideline developer as of February 20, 2001. This summary was updated by ECRI on March 31, 2003. The updated information was verified by the guideline developer on April 21, 2003. This NGC summary was updated by ECRI Institute on May 17, 2007. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on May 12, 2010.

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